

Currently Pending Claims (11/03/03)

55. A solid, dermatological composition comprising a biologically active agent dissolved in a homogeneous carrier system, wherein the carrier system includes

- a) a solvent for said active agent, comprising 20 to 85% by weight of an unsaturated fatty acid alcohol in combination with an alkylene glycol, said fatty acid alcohol being selected from oleyl alcohol, ricinolyl alcohol, linolyl alcohol and/or linolenyl alcohol, and said alkylene glycol being selected from propylene glycol and/or dipropylene glycol, the alkylene glycol being present in an amount of more than 12% by weight to provide for mutual dissolution of said active agent;
- b) a viscosity enhancing agent for imparting a solid consistency to the composition which comprises 15 to 55% by weight of a waxy substance; and
- c) a plasticizing agent which comprises 2 to 30% by weight of a plasticizing oil;

all percentages being based on the total weight of the carrier system.

56. A composition as claimed in Claim 55, wherein the amount of said alkylene glycol comprises at least 15% by weight.

57. A composition as claimed in Claim 55, wherein the biologically active agent comprises a lipophilic compound.

58. A composition as claimed in Claim 57, wherein the biologically active compound is selected from the group consisting of steroids, sex hormones, vitamins, biologically active lipids, fatty acids, antivirals, antibacterials, antiprotozoals and antifungals, and local anesthetics.

59. A composition as claimed in Claim 58, wherein the biologically active compound is selected from fluocinonide, omega-3-fatty acid and azelaic acid and salts and esters thereof.

60. A composition as claimed in Claim 58, wherein the biologically active compound is clobetasol or a salt or an ester thereof.

61. A composition as claimed in Claim 55, wherein the alkylene glycol is propylene glycol.

62. A composition as claimed in Claim 55, wherein the solvent additionally comprises propyl myristate, palmitate, and/or stearate and/or the propyl ester of sorbic acid.

63. A composition as claimed in Claim 62, wherein said additional solvent is isopropylpalmitate.

64. A composition as claimed in Claim 55, wherein the waxy substance comprises a natural and/or synthetic wax; a fat; a glycol ester of a C₁₈-C₃₆ fatty acid; or a mixture of two or more such compounds.

65. A composition as claimed in Claim 64, wherein the waxy substance comprises a combination of a natural or synthetic wax and a triglyceride and/or a glycol ester.

66. A composition as claimed in Claim 55, wherein the plasticizing oil is selected from aliphatic acids and alcohols.

67. A composition as claimed in Claim 55, wherein the amount of plasticizing oil is within the range of 2-20% by weight.

68. A composition as claimed in Claim 55, wherein the amount of solvent is within the range of 25-75% by weight.

69. A composition as claimed in Claim 55, wherein the amount of said alkylene glycol is within the range of 12-23% by weight.

70. A composition as claimed in Claim 62, wherein the weight ratio of unsaturated fatty acid alcohol : additional solvent ranges from 1:2 to 5:1.

71. A composition as claimed in Claim 55, wherein the biologically active agent is present in a concentration of up to the solubility limit thereof in the carrier system.

72. A composition as claimed in Claim 55, wherein the concentration of the biologically active agent is 0.01-10% by weight, based on the weight of the carrier system.

73. A composition as claimed in Claim 55, wherein said composition is a stick.

74. A composition as claimed in Claim 55, wherein said biologically active agent is a therapeutically or prophylactically active agent.

75. A composition as claimed in Claim 74, for topical application to the skin of a mammal, and possesses a viscosity that is adapted for such application.

76. A process for the preparation of a biologically active composition as claimed in Claim 55, comprising dissolving the biologically active agent in said solvent therefor, combining the resulting solution with the viscosity enhancing agent and the plasticizing agent so as to impart a solid consistency to said solution and shaping the resulting composition into a desired form.

77. A method of prophylactic or therapeutic treatment of a dermatological condition comprising topically applying a prophylactically or therapeutically effective amount of an

active agent containing solid composition according to Claim 55, wherein the active agent is an agent for treatment or prophylaxis of a dermatological condition.

78. The method of Claim 77, wherein the active agent is selected from the group consisting of a steroid, vitamin, biologically active lipid, fatty acid, antimicrobial, and anesthetic.

79. The method of Claim 77, wherein the active agent is selected from the group consisting of a corticosteroid, sex hormone, vitamin A, vitamin B2, vitamin B3, vitamin E, vitamin K, an antibiotic, an antiviral, anti-protozoal, antifungal, and an amide local anesthetic.

80. The method of Claim 77, wherein the active agent is selected from the group consisting of clobetasol or a salt or ether thereof, and beta-methasone or a salt or ester thereof.

81. The method of Claim 80, wherein the active agent is clobetasol propionate, methasone-17-valerate or betamethasonedipropionate.

82. A composition as claimed in Claim 55, wherein the biologically active agent is a lipophilic drug.

83. A composition as claimed in Claim 57, wherein the biologically active compound is lipophilic anesthetic of the amide type.

84. A composition as claimed in Claim 60, wherein the biologically active compound is clobetasol propionate.
85. A composition as claimed in Claim 60, wherein the waxy substance comprises a natural and/or synthetic wax that is a monoester of a long-chain carboxylic acid with a long-chain alcohol, and the fat is a triglyceride of a C₁₈-C₃₆ fatty acid.
86. A composition as claimed in Claim 55, wherein the plasticizing oil is selected from branched chain aliphatic acids and alcohols which reduce the viscosity of the carrier system.
87. A composition as claimed in Claim 55, wherein the plasticizing oil is fluid lanoline.
88. A composition as claimed in Claim 55, wherein the amount of solvent ranges from 40-60% by weight, the amount of viscosity enhancing agent ranges from 25-50% by weight, and the amount of plasticizing oil ranges from 2-20% by weight.
89. A composition as claimed in Claim 55, wherein the amount of said alkylene glycol ranges from 15-23% by weight.

90. A composition as claimed in Claim 55, wherein the amount of said alkylene glycol ranges from 12-20% by weight.

91. A composition as claimed in Claim 55, wherein the amount of said alkylene glycol ranges from 15-20% by weight.

92. A composition as claimed in Claim 62, wherein the weight ratio of unsaturated fatty acid alcohol : additional solvent is within the range of 1:2 to 3:1.

93. A composition as claimed in Claim 62, wherein the weight ratio of unsaturated fatty acid alcohol : additional solvent is within the range of 1:2 to 2:1.

94. A composition as claimed in Claim 55, wherein the concentration of the biologically active agent is 0.02-5% by weight based on the weight of the carrier system.

95. A composition as claimed in Claim 55, wherein the biologically active compound is beta-methasone, or a salt or ester thereof.

96. A composition according to Claim 55, wherein the biologically active compound is beta-methasone-17-valerate or betamethasonedipropionate.

97. The composition of Claim 58, wherein the steroid is a corticosteroid.
98. The compound of Claim 58, wherein the sex hormone is selected from the group consisting of androgens, estrogens and derivatives thereof.
99. The compound of Claim 58, wherein the vitamin is selected from the group consisting of vitamin A, D2, D3, E, K and derivatives thereof.